

DEPARTMENT OF FOOD AND AGRICULTURE

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January 9, 1998

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Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1- 123
12420 Parklawn Drive
Rockville, MC 20857

RE: Docket No. 9N-0451

Regarding the draft "Guide To Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables", the California Department of Food and Agriculture is submitting the following comments. As the nation's leading producer, with more than fifty percent of the total production of fresh fruits and vegetables, we are uniquely positioned to offer these comments.

The recent developments identifying fresh produce as a source of foodborne illnesses saw a quick and decisive movement by California's fresh fruit and vegetable industry to take a proactive role in developing programs and methodology to address the problem. California's agricultural industries have taken the initiative to address the issues related to food borne illnesses associated with the consumption of fresh fruits and vegetables. This leadership and determination to ensure the safety of their products are demonstrated by programs initiated by the industry in cooperation with government agencies in California.

Such programs are exhibited by the Apple Hill Quality Assurance Program, the Voluntary Food Safety Guidelines for Fresh Produce and the Strawberry Quality Assurance Plant which have been developed in partnership with Western Growers Association, International Food Processors Association, California Strawberry Commission, state and federal regulatory agencies, local agricultural commissioners and academia. Successful partnerships clearly demonstrate the willingness on the part of industry to take the necessary proactive steps to ensure the safety of its products.

Having participated in the process and having had the opportunity to listen and review comments made at the public meetings held by FDA, we too have some concerns and recommendations regarding the draft guidelines. Our experience in California showed that defining and implementing such guidelines is most effectively developed in an open partnership between the government agencies and industry. Industry must have a direct and active participation in the process for the partnership to work. This partnership also provides an opportunity to share information and build consensus.

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With regard to the draft "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables, the Department has concern in five specific areas. These are 1) the short time frame to adopt complex guidelines; 2) appropriate science based reasons to adopt guidelines for specific commodities; 3) lack of acknowledgment of industry's efforts to establish food safety guidelines and quality assurance programs; 4) "gaps" in the research and the need for research to answer many of the unknowns potentially affected by guidelines and 5) a lack of understanding of current industry practices in a wide array of settings and commodities.

Time Frames for Adopting Guidelines:

The Department is concerned with the time frames proposed to adopt the guidelines. As pointed out by many of the commentators at the December 8th meeting in Salinas, it is very optimistic to undertake the development and implementation of "industry wide" guidelines within a nine month time period. While we applaud the agency's initiative and fully support food safety guidelines, it is unrealistic to propose such swift action given the reality experienced by cooperative industry/government partnerships groups who have designed general guidelines for food safety for fresh produce and other commodities. Experience tells us it is necessary to adequately review all of the issues.

It would be much better in the long run to develop and approve guidelines which reflect current industry practices and experiences. In this setting, guidelines are much more likely to be implemented in a timely manner by the majority of producers and processors. It also provides an opportunity to educate regulatory officials and industry leadership.

Proposal to Adopt Commodity Specific Guidelines:

The Department is concerned with the perception associated with guidelines adopted for specific commodities if chosen for arbitrary reasons. Such action will suggest to the consumer that these commodities are not safe and in fact, pose a higher risk for microbial contamination. The negative perception associated with this action could have severe implications in the ability to effectively market the commodity. Without any science to support the action, the Department strongly recommend that any guidelines which may be adopted be limited to general guidelines without specificity. However, if certain practices are shown scientifically to increase the risk of a certain commodity, then it is appropriate to develop commodity specific guidelines.

Current and Proposed Industry Quality Assurance Programs:

While we are very proud of the partnerships and programs developed in California, and believe they have application nationally, we urge the agency to spend time studying these programs and

comparing the scope and applicability to the agencies own proposed guidelines. These programs represent bold and aggressive steps by industry leaders to establish effective food safety guidelines for fresh produce and processed commodities. These programs reflect the strong commitment by industry and regulatory agencies to forge strong and effective partnerships to encourage the adoption of programs which will minimize potential microbial contamination. Such efforts cannot be taken lightly and must be acknowledged by the agency as progressive and effective efforts. As we stated at the Salinas meeting, the staff is welcome and encouraged to come to California and go to the fields and plants, to view the practices and programs first hand.

Research Needs:

There are research gaps in many areas of the guidelines being proposed. Without adequate science to determine action, there will be increased confusion and misunderstanding on the part of industry, regulators and consumers as to what is and what should be done. Examples include general suggestions for sampling. It is one thing to suggest, but what are the critical control points which the industry needs to measure and what actions need to be taken in response to monitoring? What are the frequency of sampling, time and place and responsibilities for action when a tolerance is exceeded? These recommendations should not be made by a "best guess". We all need to cooperate to find the necessary answers.

There has been a significant amount of work done in a wide range of environments, but much remains to be done. the research must be supported cooperatively by industry and government working together. Our Department's own Food Safety Program, established to address as part of its objective, research needs and agendas may be used as a model for other states. Regardless, in the absence of good science, the value of general guidelines is greatly diminished.

Industry Practices:

The Department feels strongly that the agency should spend additional time conducting on-site visits to see first hand the programs which the fresh fruit and vegetable industry has developed and implemented. In many cases, these programs go far beyond what is being proposed as general guidelines. We recommend that such efforts need to be verified by the agency and acknowledged as effective programs which are having positive results to minimize potential exposure to microbial contamination.

It is imperative that agency representatives see first hand, industry quality assurance programs. From these types of visits, the agency can gather the needed input from affected producers and processors which is needed to accurately assess specific situations and commodity practices. Additionally, in conducting field visits, the agency can also meet its objective of conducting outreach

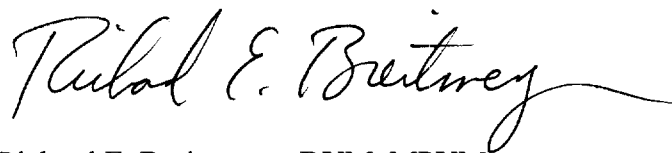
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and educational activities as part of its efforts to work with industry to facilitate gathering and adoption of guidance information in the GAPs and GMPs.

In closing, we want to express our appreciation for the opportunity to comment and to participate with the working group in drafting the guidelines. However, we continue to recommend that the time-lines be extended to give agency staff adequate time to thoroughly review all of the issues, to spend time on-site at production, packing and processing locations and to review and evaluate successful programs.

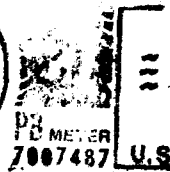
Again, we want to thank the agency both for the opportunity to comment and to participate as a member of the working group reviewing the draft guidelines.

Sincerely,

A handwritten signature in cursive script, reading "Richard E. Breitmeyer". The signature is fluid and extends to the right with a long, sweeping underline.

Richard E. Breitmeyer, DVM, MPVM
Director
Division of Animal Industry

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